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**PATENT**

Attorney Docket No.: 34471/US/3/AMP/SKS

Attorney File No.: 459258-00014

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* application of:

GALLOP

Serial No. 10/734,631

Filing Date: December 11, 2003

For: *Orally Administered Dosage Forms  
of Fused GABA Analog Prodrugs  
Having Reduced Toxicity*

Examiner: Not Assigned

Art Unit: 1614

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

Dated: October 21, 2004

Signed: [Signature]

Luke Szymanski

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. In accordance with 1273 Off. Gaz. Pat. Off. 1, 8/5/2003, no copies of U.S. patents and U.S. published applications are enclosed.

Further, in accordance with the provisions of 37 C.F.R. §§ 1.97(c) and 1.97(e)(1), the undersigned certifies that references WO 02/090318 A1 (Warner-Lambert Company) and WO 02/085839 A1 (Warner-Lambert Company) listed on the enclosed substitute for form PTO-1449 were first cited in an International Search Report dated September 24, 2004, for a counterpart

Serial No. 10/734,631

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PCT application. As such, the filing of the instant Information Disclosure Statement is within three months of the date of that International Search Report and, therefore, need not be accompanied by the fee. A copy of the International Search Report for the counterpart PCT application is enclosed herewith.

None of the foregoing references are believed to disclose the invention as claimed. Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application. Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

Serial No. 10/734,631

Filing Date: December 11, 2003

As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required. While no additional fee is believed to be due, if this belief is in error the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 459258-00014 [34471/US/3/AMP/SKS]).

Respectfully submitted,

DORSEY & WHITNEY LLP

Dated: 10/20/04

Customer Number: 32940

Dorsey & Whitney LLP

Intellectual Property Department

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By:

Sunil K. Singh  
Sunil K. Singh, Reg. No. 45,298

Attachments : Form PTO/SB/8A, Substitute for form 1449  
International Search Report  
46 cited references  
Return Postcard



<b>Substitute for form 1449A/PTO (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/734,631
				Filing Date	December 11, 2003
				First Named Inventor	Gallop, Mark A.
				Art Unit	1614
				Examiner Name	Not Assigned
Sheet	1	of	5	Attorney Docket Number	34471/US/3/AMP/SKS (459258-00014)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	2,996,431	08-15-1961	Barry	
	A2	3,139,383	06-30-1964	Neville	
	A3	3,402,240	09-17-1968	Cain <i>et al.</i>	
	A4	3,811,444	05-21-1974	Heller <i>et al.</i>	
	A5	3,916,899	11-04-1975	Theeuwes <i>et al.</i>	
	A6	3,845,770	11-05-1974	Theeuwes <i>et al.</i>	
	A7	3,916,899	11-04-1975	Theeuwes <i>et al.</i>	
	A8	3,962,414	06-08-1976	Michaels	
	A9	3,992,518	11-16-1976	Chien <i>et al.</i>	
	A10	4,024,175	05-17-1977	Satzinger <i>et al.</i>	
	A11	4,063,064	12-13-1977	Saunders <i>et al.</i>	
	A12	4,066,747	01-03-1978	Capozza	
	A13	4,070,347	01-24-1978	Schmitt	
	A14	4,079,038	03-14-1978	Choi <i>et al.</i>	
	A15	4,083,949	04-11-1978	Benedikt	
	A16	4,087,544	05-02-1978	Satzinger <i>et al.</i>	
	A17	4,088,864	05-09-1978	Theeuwes <i>et al.</i>	
	A18	4,093,709	06-06-1978	Choi <i>et al.</i>	
	A19	4,285,987	08-25-1981	Ayer <i>et al.</i>	
	A20	4,421,736	12-20-1983	Walters	
	A21	4,434,153	02-28-1984	Urquhart <i>et al.</i>	
	A22	4,721,613	01-26-1988	Urquhart <i>et al.</i>	
	A23	4,752,470	06-21-1988	Mehta	
	A24	4,820,523	04-11-1989	Shtohryn <i>et al.</i>	
Examiner Signature				Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
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			Art Unit	1614	
			Examiner Name	Not Assigned	
Sheet	2	of	5	Attorney Docket Number	34471/US/3/AMP/SKS (459258-00014)

U.S. PATENT DOCUMENTS					
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	A25	4,816,263	05-28-1989	Ayer <i>et al.</i>	
	A26	4,853,229	08-01-1989	Theeuwes	
	A27	5,084,479	01-28-1992	Woodruff	
	A28	5,563,175	10-08-1996	Silverman <i>et al.</i>	
	A29	6,001,876	12-14-1999	Singh	
	A30	6,020,370	02-01-2000	Horwell <i>et al.</i>	
	A31	6,024,977	02-15-2000	Yatvin <i>et al.</i>	
	A32	6,028,214	02-22-2000	Silverman <i>et al.</i>	
	A33	6,103,932	08-15-2000	Horwell <i>et al.</i>	
	A34	6,117,906	09-12-2000	Silverman <i>et al.</i>	
	A35	6,171,615	01-09-2001	Roussin <i>et al.</i>	
	A36	6,375,987	04-23-2002	Farah <i>et al.</i>	
	A37	6,379,700	04-30-2002	Joachim <i>et al.</i>	
	A38	10/710,127	06-11-2002	Gundy <i>et al.</i>	
	A39	10/171,485	06-11-2002	Gallop <i>et al.</i>	
	A40	10/167,197	06-11-2002	Gallop <i>et al.</i>	

Examiner Signature		Date Considered	
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Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1	EP 1,178,034 A1	02-05-2002	Warner Lambert Co.		
	B2	EP 1,201,240 A2	05-02-2002	Warner Lambert Co.		
	B3	GB 2,362,646 A	11-28-2001	Warner Lambert Co.		
	B4	WO 92/09560 A1	06-11-1992	Univ. Northwestern		
	B5	WO 93/23383 A1	11-25-1993	Univ. Northwestern		
	B6	WO 97/29101 A1	08-14-1997	Warner Lambert Co.		
	B7	WO 97/33858 A1	09-18-1997	Warner Lambert Co.		
	B8	WO 97/33859 A1	09-18-1997	Warner Lambert Co.		
	B9	WO 98/17627 A1	04-30-1998	Warner Lambert Co.		
	B10	WO 99/08671 A1	02-25-1999	Warner Lambert Co.		
	B11	WO 99/21824 A1	05-06-1999	Warner Lambert Co.		
	B12	WO 99/31057 A1	06-24-1999	Warner Lambert Co.		
	B13	WO 99/31074 A2/A3	06-24-1999	Warner Lambert Co.		
	B14	WO 99/31075 A1	06-24-1999	Warner Lambert Co.		
	B15	WO 99/37296 A1	07-29-1999	Warner Lambert Co.		
	B16	WO 99/61424 A1	12-02-1999	Warner Lambert Co.		
	B17	WO 00/15611 A1	03-23-2000	Warner Lambert Co.		
	B18	WO 00/23067 A1	04-27-2000	Warner Lambert Co.		
	B19	WO 00/31020 A1	06-02-2000	Warner Lambert Co.		
	B20	WO 00/50027 A1	08-31-2000	Warner Lambert Co.		
	B21	WO 01/90052 A1	11-29-2001	Warner Lambert Co.		
	B22	WO 02/00209 A2/A3	01-03-2002	Warner Lambert Co.		
	B23	WO 02/085839 A1	10-31-2002	Warner Lambert Co.		

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Substitute for form 1449A/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	10/734,631	
			Filing Date	December 11, 2003	
			First Named Inventor	Gallop, Mark A.	
			Group Art Unit	1614	
			Examiner Name	Not Assigned	
Sheet	4	of	5	Attorney Docket Number	34471/US/3/AMP/SKS (459258-00014)

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document Country Code* Number* Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B24	WO 02/28881 A1	04-11-2002	XenoPort, Inc.		
	B25	WO 02/28883 A1	05-11-2002	XenoPort, Inc.		
	B26	WO 02/28411 A1	04-11-2002	XenoPort, Inc.		
	B27	WO 02/32376 A1	04-25-2002	XenoPort, Inc.		
	B28	WO 02/42414 A2/A3	05-30-2002	XenoPort, Inc.		
	B29	WO 02/090318 A1	11-14-2002	Warner Lambert Co.		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C1	Alderman, "A Review of Cellulose Ethers in Hydrophilic Matrices or Oral controlled-Release Dosage Forms," <i>Int. J. Pharm. Tech. &amp; Prod. Mfr.</i> 1984, 5(3) 1-9.	
	C2	Bamba <i>et al.</i> , "Release Mechanisms in Gelforming Sustained Release Preparations," <i>Int. J. Pharm.</i> 1979, 2, 307.	
	C3	Coleman <i>et al.</i> , "Polymer Review: A Practical Guide to Polymer Miscibility," <i>Polymers</i> 1990, 31, 1187-1231.	
	C4	During <i>et al.</i> , "Controlled release of dopamine from a polymeric brain implant: in vivo characterization," 1989, <i>Ann. Neurol.</i> 25:351.	
	C5	Fincher, "Particle Size of Drugs and Its Relationship to Absorption and Activity," <i>J. Pharm. Sci.</i> 1968, 57, 1825-1835.	
	C6	Goodson, "Medical Applications of Controlled Release," vol. 2, pp. 115-138 (1984).	
	C7	Hoes <i>et al.</i> , "The Application of Drug-Polymer Conjugates in Chemotherapy," <i>Drug Carrier Systems</i> 1989, 9, 57-110.	
	C8	Howard <i>et al.</i> , "Intracerebral drug delivery in rats with lesion-induced memory deficits," <i>J. Neurosurg.</i> 1989 71(1):105-112.	
	C9	Langer <i>et al.</i> , "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," <i>J Macromol. Sci. Rev. Macromol Chem.</i> 1983, 23:61.	
	C10	Langer, "New Method of Drug Delivery," 1990, <i>Science</i> 249:1527-1533.	
	C11	Leong <i>et al.</i> , "Polymeric Controlled Drug Delivery," <i>Adv. Drug Delivery Rev.</i> 1987, 1, 199-233.	
	C12	Levy <i>et al.</i> , "Inhibition of Calcification of Bioprosthetic Heart Valves by Local Controlled-Release Diphosphonate," <i>Science</i> 1985 228: 190.	

Examiner Signature	Date Considered
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	† <sup>6</sup>
	C13	Lu, "Dimensionless Presentation for Drug Release From a Coated Pure Drug Bead: 2 Experiment," <i>Int. J. Pharm.</i> , 1994, 112, 117-124.	
	C14	Peto <i>et al.</i> , "The TD50: a proposed general convention for the numerical description of the carcinogenic potency of chemicals in chronic-exposure animal experiments," <i>Environmental Health Perspectives</i> 1984, 58, 1-8.	
	C15	Saudek <i>et al.</i> , "A Preliminary Trial of the Programmable Implantable Medication System for Insulin Delivery," <i>N. Engl. J. Med.</i> , 1989, 321: 574.	
	C16	Sefton, "Implantable Pumps," <i>CRC Crit Ref Biomed. Eng.</i> 1987, 14:201.	
	C17	Verma <i>et al.</i> , "Osmotically Controlled Oral Drug Delivery," <i>Drug Dev. Ind. Pharm.</i> , 2000, 26:695-708.	

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